# Study Adoption Request Form

## **Terms**

The terms of study adoption for the network are as follows:

1. Keep the HRB Primary Care CTNI up to date

Research teams we support must provide and update information about their studies for the HRB Primary Care CTNI. This includes a summary of your project, information for our website, information about the study design, the organisation that is funding the research and contact details. You must also supply (on request, usually once a quarter) brief information about key progress milestones (e.g. practices/patients recruited) and any learnings useful to the Network. This will help the Network manage future communication with and recruitment of practices into different studies.

1. *Acknowledge HRB Primary Care CTNI support*

We also expect you to acknowledge HRB Primary Care CTNI support on any material you produce about your study, including information for participants, websites and papers published in academic journals. Please contact us for logos.

1. *Help build a stronger network*

The study team are also requested to invite any practices they recruit from their study *that are not from the network* to register with the network, in order to streamline future practice recruitment of research-active practices. <https://primarycaretrials.ie/healthcareprofessionals/register-with-us/>

## **Application**

|  |  |
| --- | --- |
| **Study name:**  |  |
| **Study Lead:** |  |
| **Affiliation:** |  |
| **Contact details team:** |  |
| **Study funded by:**  |  |
| **Date of application**  |  |

 **Background:**

**Primary study objective(s):**

**Study timeline:**

|  |  |
| --- | --- |
| **Funding status and source** |  |
| **Ethical approval status and details of awarding body** |  |
| **HPRA status (if applicable)** |  |
| **Current status of study** |  |

**If you wish to recruit practices through the HRB Primary Care CTNI, please specify:**

|  |  |
| --- | --- |
| **Number of practices** |  |
| **Country, region** |  |
| **Specific requirements (size, PN required? Etc)** |  |
| **What does study require practice staff to do?**  |  |
| **Target recruitment per practice**  |  |
| **Financial and other supports to practices** |  |
| **When will practice recruitment begin?**  |  |

**Who are potential participants**?

|  |  |
| --- | --- |
| **Main patient inclusion criteria**  |  |
| **Any significant exclusion criteria** |  |
| **What does the study involve for participants (number of visits/where to/IMPs/other interventions/financial)?**  |  |

Please include here any other significant study information that will help the Study Adoption Panel understand the study.

Please also forward the study protocol with this Study Adoption Request form.

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# Criteria for study adoption

The Study Adoption Panel will consider the following questions when assessing a request:

1. Does the study involve recruitment and/or advertising through general practice or primary care centres?
2. Is the study a pilot or a trial, or is it gathering data that may be used/useful when designing a trial in the future?
3. Does the study investigator and team have an acceptable track-record?
4. Is there a confirmed funding source and does the sponsor have an acceptable track-record?
5. Does the study have ethical approval granted and is the study GDPR-compliant (with supporting documentation)?
6. Are there potential risks to the Network?
7. Does the protocol include any procedures that the adoption panel believe will jeopardise the study?
8. Does the study improve patient care or have the potential to improve patient care in the future?
9. Is the study compatible with primary care practice in Ireland; is the prevalence of the target patient population sufficient for recruitment?
10. Does the HRB Primary Care CTNI have the capacity to provide requested resources?
11. Are there conflicting trials ongoing within the Network or higher priority studies pending?

Phase IV studies are usually, but not invariably, considered ineligible.

**Checklist**:

[ ] Study Adoption Request form

[ ] Study protocol

[ ] Copy of Ethical approval and statement of GDPR compliance

[ ] Signature Page

Signature Page

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| Applicant I am submitting this study adoption request form to the HRB Primary Care CNTI. I confirm that if adoption is successful, I will agree to the terms described at the beginning of the document.Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Name (Printed): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |